Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

The effect of Nurse-led Cognitive Behavioral Therapy (CBT) program on depression and sleep quality in patients undergoing open heart surgery

Protocol summary

Study aim
The effect of Nurse-led Cognitive Behavioral Therapy (CBT) program on depression and sleep quality of patients undergoing open heart surgery

Design
A randomized, double-blind, parallel group, controlled clinical trial, For random assignment, each end-participant of the research is first given a code of 1 to 84(sample size) and then using R software and sample instruction, 42 code out of 84 codes will be selected as the intervention group and the rest of the numbers will represent the control group code.

Settings and conduct
The target population was all patients with open heart surgery who referred to Shiraz Kowsar Hospital. During the interview and if the consent is obtained, the presence or absence of depression in patients with the use of DISH tool and its severity is evaluated using the Beck Depression Instrument. If the illness did not have symptoms of depression in the initial interview with Beck or had partial depression, then a second interview would be done to her after 4 weeks of discharge. If the patient showed complete depression symptoms in the second interview, he / she will be randomly assigned to either test or control group.

Participants/Inclusion and exclusion criteria
The main entry conditions include the incidence of depression and sleep disorder after open heart surgery and the main incontinence conditions including the incidence of depression and sleep disorder before open heart surgery

Intervention groups
The intervention group: have some degree of depression and post-operative sleep disturbance, in addition to routine care at the treatment center, for whom CBT protocol will also be considered. The control group included those who, based on the tools used, developed some degree of depression and post-operative sleep disturbance and received only routine care in the treatment center.

Main outcome variables
Depression, Sleep Disturbance

General information

Reason for update

Acronym
CBT

IRCT registration information
IRCT registration number: **IRCT20190717044252N1**
Registration date: **2019-11-10, 1398/08/19**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-10, 1398/08/19**
Update count: **0**

Registration date
2019-11-10, 1398/08/19

Registrant information

Name
Elham Hosseini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3631 5484

Email address
ehosseini@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-06, 1398/05/15

Expected recruitment end date
2019-12-21, 1398/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Nurse-led Cognitive Behavioral Therapy (CBT) program on depression and sleep quality in patients undergoing open heart surgery

Public title
The effect of Cognitive Behavioral Therapy (CBT) program on depression and sleep quality
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Ability to attend counseling sessions Minimum diploma education Age between 20 and 65 years Stay in shiraz Full vigilance and ability to speak Persian Physical and mental fitness required to answer questions Not attending other training courses at the same time Not having a specific psychiatric condition before surgery Having Depression After Heart Surgery Having a sleep disorder after heart surgery
Exclusion criteria:
The unwillingness of the subject to participate or continue to participate in the research Cases of other diseases, including malignancies or autoimmune disorders Facing specific mental crises before surgery Treated with sedative drugs before surgery
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
For random assignment, at first, each of the final participants will be given a sample of one to 84 (sample size), then using the software R and the sample command, 42 of the code are selected from 84 codes as the intervention group, and the remaining numbers represent The code will be the control group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The days of referral in the intervention group for counseling are different with the days of referral of patients in the control group.
Placebo
Not used
Assignment
Parallel
Other design features
The highlight of the above study is the implementation of a cognitive behavioral therapy program by a trained Nursing Specialist.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee of the Faculty of Nursing and Midwifery and Rehabilitation of Tehran University
Street address
No. 29, 11 Ave., Shahidan Gerami Ave., Farhang Shahr Ave., Shiraz
City
Shiraz
Province
Fars
Postal code
7187665736
Approval date
2019-06-19, 1398/03/29
Ethics committee reference number
IR.TUMS.FNM.REC.1398.043

Health conditions studied

1

Description of health condition studied
Depression
ICD-10 code
F32.1
ICD-10 code description
Moderate depressive episode

2

Description of health condition studied
Sleep Disorder
ICD-10 code
F51
ICD-10 code description
Nonorganic sleep disorders

Primary outcomes

1

Description
Depression Score in Beck Questionnaire
Timepoint
The beginning of the study and the end of the intervention
Method of measurement
Beck Depression Inventory

2

Description
sleep disorder
Timepoint
The beginning of the study and the end of the intervention
Method of measurement
Pittsburgh Sleep Quality Index (PSQI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Cognitive behavioral intervention group or CBT. Intervention group includes those who have mild to moderate degrees of post-operative depression based on the tools used and will receive CBT protocol in addition to routine care at the treatment center. The CBT protocol will consist of 10 to 12 one-hour weekly sessions, when the patient is indicated, by a trained nurse and in an appropriate pre-embedded location. There will be interactions, discussions, assignments and feedback. Weekly focal points are as follows: Week One: Establish a therapeutic relationship, set a meeting schedule, identify problems objectively, and set treatment goals. Week 2: Increasing patient knowledge, activating behavioral functions, and problem solving techniques. Week 3-4: Identifying automatic thoughts, improving problem-solving skills, reducing ineffective cognitive processes on behavior. Week 5-6: Reconstructing automatic thoughts, identifying abilities, and learning self-treatment techniques. Weeks 7 to 8: Continue self-treatment and relapse prevention. Week 9 - 10: Training to improve self-care skills in the field of illness and to increase acceptable activity according to disease conditions, end Intervention and discontinuation of therapeutic relationship. In this intervention, two sessions were considered as floating to complete the questionnaire or if needed for a longer session and need to continue the intervention.
Category
Behavior

2

Description
Control group:The control group includes those who receive only routine post-cardiac care routine care. Routine and routine care, including routine medical and nursing follow-up after cardiac surgery and psychiatric evaluation of a patient by a psychiatrist only if necessary, and requesting a psychiatric consultation by the ICU cardiologist.cognitive intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz, Kowsar Hospital
Full name of responsible person
Elham Hosseini
Street address
Kowsar Hospital., Qasr-Dasht St., Shiraz
City
Shiraz
Province
Fars
Postal code
۷۱۸۷۷۹۵۹۴۱
Phone
+98 71 3614 1000
Email
elhamh765@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
MOHAMMAD ALI SAHRAIAN
Street address
Sina Hospital., Imam Khomeini Ave., Hasan Abad Sq., Tehran
City
Tehran
Province
Tehran
Postal code
1136746911
Phone
+98 21 6670 6142
Fax
+98 21 6670 6141
Email
msahrai@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Elham Navab
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Faculty of Nursing and Midwifery., Dr Mirkhani St., Tohid Square.,Tehran
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4000
Email
e_navab100@hotmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Elham Navab
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Faculty of Nursing and Midwifery., Dr Mirkhani St., Tohid Square.,Tehran
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4000
Email
e_navab100@hotmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Elham Hosseini
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Anesthesiology
Street address
No.29., 11Ave., Shahidan Gerami Ave., Farhang Shahr Ave., Shiraz
City
Shiraz
Province
Fars
Postal code
7187665736
Phone
+98 71 3631 5484
Fax
Email
ehosseini@razi.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available